The following corrections or additions to the January 15, 1997 list were made in February, 1997

New Approvals

ANADA Number: 200-136

Pioneer Product:	065-496
Trade Name:	Tetracycline Hydrochloride Soluble Powder-324
Ingredients:	Tetracycline hydrochloride
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	12/17/96
Status:	Over-the-counter
Route:	Oral
Species:	Bovine (calves), porcine, avian (chickens, turkeys)
Drug Form:	Powder
Concentration:	324 g/lb
Indications:	For use in the control and treatment of the following conditions in swine, calves and poultry: Swine: bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia associated with *Pasteurella* spp., *Hemophilus* spp. and *Klebsiella* spp. susceptible to tetracycline. Calves: bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia (Shipping fever) associated with *Pasteurella* spp., *Hemophilus* spp. and *Klebsiella* spp. susceptible to tetracycline. Chickens: control of chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli*; infectious synovitis caused by *Mycoplasma synoviae* susceptible to tetracycline. Turkeys: control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to tetracycline; control of bluecomb (transmissible enteritis, coronaviral enteritis) complicated by organisms sensitive to tetracycline.
Tolerance :	21CFR 556.720: 2 ppm for muscle, 6 ppm for liver, and 12 ppm for kidney and fat.
Withdrawal:	Calves: 5 days; swine, chickens and turkeys: 4 days

21CFR 520.2345d

ANADA Number : 200-165

Pioneer Product :	031-205
Trade Name :	SDM Sulfadimethoxine 12.5% Oral Solution
Ingredients :	Sulfadimethoxine
Sponsor :	Fermenta Animal Health Co.
Approval Date :	12/04/96
Status :	Over-the-counter
Route :	Oral
Species :	Bovine, avian (broiler and replacement chickens, meat producing turkeys, dairy calves and heifers, and beef cattle).
Drug Form :	Liquid (solution)
Concentration :	3.75 g/fluid ounce (12.5%)
Indications :	Chickens: coccidiosis, fowl cholera, and coryza. Turkeys: coccidiosis and fowl cholera. Cattle: shipping fever complex, bacterial pneumonia, calf diphtheria, and foot rot.
Tolerance :	21CFR 556.640: 0.1 ppm for the uncooked edible tissues of chickens, turkeys, and cattle.
Withdrawal :	Chickens and turkeys: 5 days; cattle: 7 days.

21CFR 520.2220a

NADA Number : 141-078

Trade Name :	Heartgard™ for Cats
Ingredients :	Ivermectin
Sponsor :	Merck Research Laboratories, Div. of Merck & Co., Inc.
Approval Date :	12/23/96
Status :	Prescription Only
Route :	Oral
Species :	Feline
Drug Form :	Chewable tablets
Concentration :	55 mcg and 165 mcg/chewable tablet
Indications :	To prevent feline heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for a month (30 days) after infection, and for the removal and control of adult and immature (L4) hookworms (*Ancylostoma tubaeforme* and *A. braziliense*).
Exclusivity :	3 years

21CFR 520.1193

NADA Number : 141-074

Trade Name:	Trexonil™
Ingredients:	Naltrexone hydrochloride
Sponsor:	Wildlife Laboratories, Inc.
Approval Date:	12/23/96
Status:	Prescription Only
Route:	Intravenous and subcutaneous
Species:	Cervidae (elk and moose)
Drug Form:	Liquid (solution)
Concentration :	50 mg/mL
Indications:	For use as an antagonist to carfentanil citrate immobilization in free ranging or confined elk and moose (Cervidae).
Exclusivity:	5 years

21CFR 522.1465

Supplemental Approvals

NADA Number: 140-929

Trade Name:	Micotil® 300
Ingredients:	Tilmicosin phosphate
Sponsor :	Elanco Animal Health
Approval Date:	12/30/96
Status:	Prescription Only
Route:	Subcutaneous
Species:	Bovine (feedlot cattle)
Drug Form:	Liquid (solution)
Concentration:	300 mg/mL
Indications :	For the treatment of bovine respiratory disease (BRD) associated with *Pasteurella haemolytica.* For the control of respiratory disease in cattle at high risk of developing BRD associated with *P. haemolytica*.
Tolerance :	21CFR 556.735: 1.2 ppm for parent tilmicosin (marker residue) in liver (target tissue) of cattle.
Withdrawal :	Not established. Do not used in calves to be processed for veal. Do not slaughter within 28 days of last treatment.
Patent Number:	4,820,695 Expiration date: 04/11/2006
Exclusivity:	3 years

This supplemental application provides for the use of tilmicosin phosphate in cattle for a new therapeutic claim.

21CFR 522.2471

NADA Number : 141-026

Trade Name :	Program® Suspension
Ingredients :	Lufenuron
Sponsor :	Ciba-Geigy Corporation
Sponsor No :	058198
Approval Date :	12/31/96
Status:	Over-the-counter
Drug Form:	Oral
Species:	Feline
Route:	Liquid (suspension)
Concentration :	135 mg and 270 mg lufenuron/unit dose pack
Indications :	For use in cat and kittens, six weeks or older, for the control of flea populations.

This supplemental application provides for a change from prescription-only (Rx) to over-the-counter (OTC) status and the addition of an Adverse Reactions section to the labeling.

21CFR 520.1289

NADA Number : 141-035

Trade Name:	Program® Tablets
Ingredients:	Lufenuron
Sponsor:	Ciba-Geigy Corporation
Approval Date :	12/31/96
Status:	Over-the-counter
Drug Form:	Oral
Species:	Canine
Route:	Tablets
Concentration :	45 mg, 90 mg, 204.9 mg, and 409.8 mg/tablet
Indications:	For use in dogs and puppies, six weeks of age and older, for the prevention and control of flea populations.

This supplemental application provides for a change from prescription-only (Rx) to over-the-counter (OTC) status and the addition of an Adverse Reactions section to the labeling.

21CFR 520.1288

NADA Number: 110-315

Trade Name:	Implus-C®
Ingredients:	Progesterone, estradiol benzoate
Sponsor:	Ivy Laboratories, Inc.
Approval Date:	01/22/97
Status:	Over-the-counter
Route:	Subcutaneous
Species:	Bovine
Drug Form:	Ear implant
Concentration :	25 mg progesterone and 2.5 mg estradiol benzoate/pellet.
Indications:	For increased rate of weight gain in suckling beef calves up to approximately 400 lbs body weight.
Exclusivity:	3 years

This supplemental application provides for the deletion of the labeling limitation against the use of Implus-C in heifer (suckling beef) calves intended for reproduction.

21CFR 522.1940

NADA Number: 138-792

Trade Name:	MGA® 100/200 Premixes Rumensin® Tylan®
Ingredients:	Melengestrol acetate, monensin sodium, tylosin phosphate
Sponsor:	Pharmacia & Upjohn Co.
Approval Date:	12/17/96
Status:	Over-the-counter
Route:	Oral
Species:	Bovine (cattle, heifers fed in confinement for slaughter)
Drug Form:	Dry premixes
Concentration :	MGA:0.0000276-0.00022% Monensin sodium: 50-1200 g/ton Tylosin phosphate: 90-360 g/ton
Indications:	For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and reduced incidence of liver abscesses in heifers fed in confinement for slaughter.

This supplemental application provides for the co-administration of MGA, monensin and tylosin to heifers fed in confinement for slaughter when all three drugs are contained in a common Type B meal feed.

21CFR 558.342

NADA Number: 141-034

Trade Name:	Flavomycin
Ingredients:	Bambermycins
Sponsor:	Hoechst-Roussel Agri-Vet Co.
Approval Date :	11/01/96
Status:	Over-the-counter
Route:	Oral
Species:	Bovine (cattle fed in confinement for slaughter)
Drug Form:	Type B liquid medicated feed
Concentration :	40-800 g/ton
Indications :	For increased rate of weight gain and improved feed efficiency.

This supplemental application provides for the use of liquid bambermycins Type B medicated feeds to make Type C medicated feeds for cattle fed in confinement for slaughter.

21CFR 558.95

Change of Sponsor

NADA Number: 131-806

From Biocraft Laboratories, Inc. to

Teva Pharmaceuticals USA,
650 Cathill Rd., Sellersville, PA 18960.
Drug labeler code: 000093

Codification of Two Supplemental New Animal Drug Applications

The previously approved supplemental new animal drug applications, NADA 55-087 and 55-088 filed by Pfizer, Inc., which provided for the use of amoxicillin boluses and soluble powder in preruminating calves including veal calves were codified under 21 CFR 520.88d (NADA 55-088) and 520.88e (NADA 55-087). In addition, the term "nonruminating" is being changed to "preruminating" to better describe the type of animal being treated. The products are indicated for the treatment of bacterial enteritis when due to susceptible *Escherichia coli* in preruminating calves including veal calves.